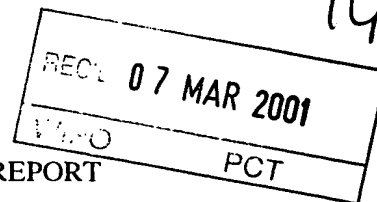


PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 18512-2020PC	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/04441	International filing date (day/month/year) 22 February 2000 (22.02.2000)	Priority date (day/month/year) 23 February 1999 (23.02.1999)
International Patent Classification (IPC) or national classification and IPC IPC(7): C07K 1/00 and US Cl.: 530/350		
Applicant ICAGEN, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 11 September 2000 (11.09.2000)	Date of completion of this report 03 January 2001 (03.01.2001)
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer <i>Christina Lawrence</i> Ulrike Winkler, Ph.D. Telephone No. (703) 308-0196

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-61 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the claims:
pages 62-69 as originally filed
pages NONE as amended (together with any statement) under Article 19
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the drawings:
pages 1-8 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the sequence listing part of the description:
pages 70-72 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☒ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☒ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☒ not complied with for the following reasons:

Please See Continuation Sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
☒ the parts relating to claims Nos. 1-13, 15, 23 and 24

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/04441

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No Patent No.	Publication Date (day/month/year)	Filing Date (day/month/year)	Priority date (valid claim) (day/month/year)
WO200012711-A2	09 March 2000 (09.03.2000)	02 September 1999 (02.09.1999)	02 September 1998 (02.09.1998)
WO200006183-A1	10 February 2000 (10.02.2000)	27 July 1999 (27.07.1999)	27 July 1998 (27.07.1998)

2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>1-15, 23 and 24</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-15, 23 and 24</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-15, 23 and 24</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS (Rule 70.7)

Claims 1-15, 23 and 24 meet the criteria set out in PCT Articles 33(2) and (3), because the prior art does not teach or fairly suggest the amino acid and nucleotide sequences of human BK beta 2,3 and 4 set out in SEQ ID NO: 1-6. The prior art discloses the expression and distribution of voltage-gated potassium channel β -subunits from rat brain (Rettig et al. Nature Vol. 369, 1994; Rhodes et al. Journal of Neuroscience Vol. 16, 1996). Although the art provides motivation to look for the human analogue of the voltage-gated potassium channel, the art does not specifically teach the sequences set out in SEQ ID NO: 1-6. Therefore, in light of the cited prior art, the subject matter of claims 1-13, 15, 23 and 24 is novel and inventive as required by Articles 33(2) and (3).

Claims 1-15, 23 and 24 have industrial applicability as set forth in PCT Article 33 (4).

----- NEW CITATIONS -----
none

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

IV. 3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-15, 23 and 24, drawn to isolated nucleic acids, expression vectors and a method of detecting the nucleic acid.

Group II, claims 16-21, drawn to polypeptides.

Group III, claim 22, drawn to antibodies.

Group IV, claims 25-32, drawn to a method of identifying a compound that increases or decreases the flux of the potassium channel.

Group V, claims 33-41 and 49-56, drawn to a method of identifying the potassium channel subunits in a sample

Group VI, claim(s) 42-48, drawn to a method of computer modeling compounds that interact with the potassium channel.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under unity of invention practice, unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

- A) A product and a special process of manufacture of said product.
- B) A product and a process of use of said product.
- C) A product, a special process of manufacture of said product, and a process of use of said product.
- D) A process and an apparatus specially designed to carry out said process.
- E) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and a method of making a product as claimed in the instant application.

Accordingly, Groups I-VI are not so linked as to form a single general inventive concept.

Supplemental Box

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Group II, claims 16-21, drawn to polypeptides.

Group III, claim 22, drawn to antibodies.

Group IV, claims 25-32, drawn to a method of identifying a compound that increases or decreases the flux of the potassium channel.

Group V, claims 33-41 and 49-56, drawn to a method of identifying the potassium channel subunits in a sample

Group VI, claim(s) 42-48, drawn to a method of computer modeling compounds that interact with the potassium channel.

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- B) A product and a process of use of said product.
- C) A product, a special process of manufacture of said product, and a process of use of said product.
- D) A process and an apparatus specially designed to carry out said process.
- E) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and a method of making a product as claimed in the instant application.

Accordingly, Groups I-VI are not so linked as to form a single general inventive concept.